Docket No. 10621-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Clarke et al
Serial No. 09/976,987
Filing Date: Oct. 12, 2001
Title: Gas-permeable Membrane

Group Art Unit: 1772
Examiner Rhee, Jane J

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Commissioner for Patents
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APPEAL BRIEF

1. Real Party in Interest

The real party in interest is the assignee, Landec Corporation.

2. Related Appeals and Interferences

There are no related appeals and interferences.

3. Status of claims

Claims 1-8, 11-16 and 20-31 are pending; of these claims, claims 12, 14 and 27 have been withdrawn. Claims 9, 10 and 17-19 have been cancelled. Claims 32 and 33 were not entered. [The Final Rejection lists the pending claims as claims 1-8, 11, 13, 15, 16, 20-26 and 28-31. However, that is not correct, since claims 12, 14 and 27,

although withdrawn because they exclude the elected species of claims 11 and 26, have not been canceled.]

Claims 1-8, 11, 13, 15, 16, 20-26 and 28-31 are the appealed claims. If the Terminal Disclaimer is entered and the double patenting rejections are in consequence withdrawn, the appealed claims will be the claims rejected under 35 USC 102 and 103, namely claims 1-8, 11, 13, 15-16, 20-26, 28, 30 and 31. Appellant notes that claim 29 has not been rejected under 35 USC 102 or 35 USC 103.

4. Status of Amendments

A paper requesting amendment of claims 1 and 20 is being filed with this Appeal Brief. As noted below, if the requested amendments are made, it will remove one of the issues (the rejection of claims 1 and 20 under 35 USC 112) from this appeal.

5. Summary of Invention

The invention relates to gas-permeable membranes comprising a microporous film and a polymeric coating on the microporous film, and the use of such membranes as atmosphere control members in packages for respiring biological materials. The claims of the present application are based on Applicants' discovery of the importance of the size and distribution of the pores in the microporous film, in particular the desirability of using pores that are not too large and not too widely distributed. The nature of the polymeric coating is not significant to the patentability of the appealed claims under 35 USC 102 and 103 in this appeal.

Page 4, lines 17-25, of the specification reads:

The size and distribution of the pores in the microporous film are important factors. If the pores are too small, the coating polymer tends to form a continuous layer which is either too thin to be durable under routine handling, or too thick to have an acceptable OTR (i.e. oxygen transmission rate). If the pores

are too large, the coating polymer may be unable to bridge over them, so that the coating plays little or no part in determining the permeability characteristics of the membrane. This may happen even if the average pore size is relatively low, if the pore have a wide range of sizes; for example the coating polymer may effectively block many of the pores, but still fail to block the larger pores, whose permeability then dominates the permeability of the membrane as a whole.

The application contains two independent claims, claims 1 and 20, which define the discovery set out above in different ways. Both independent claims require that the pores have an average pore size of less than 0.24 micron. However, this requirement is not in itself a sufficient definition, and Applicants do not contend, for the purposes of this Appeal, that it is important to the rejections of the claims.

Claim 1 defines the microporous film as one that has been made by a particular process. Claim 1 reflects the Applicants' discovery that microporous films made by that process (providing they have an average pore size of less than 0.24 microns) inherently have pores of desirable size and distribution. The process (as more fully defined in claim 1) involves the steps of the

(A) preparing a mixture of a powdered polymer, a filler and a processing oil;

(B) extruding the mixture as a sheet;

(C) forwarding the sheet, without drawing, to heated calender rolls;

(D) passing the sheet through the calender rolls;

(E) removing the processing oil from the sheet by contacting it with an organic extraction liquid;

(F) removing the extraction liquid from the sheet by steam or water; and

(G) removing residual water and extraction liquid from the sheet with a forced air dryer.

Claim 20 defines the pore size and distribution of the microporous film directly, by requiring (in addition to an average pore size of less than 0.24 micron) that

at least 70% of the pores have a pore size of less than 0.24 micron,

less than 20% of the pores have a pore size less than 0.014 micron, and at least 80% of the pores have a pore size less than 0.15 micron.

Thus, claim 20 puts quantitative limits on the general principle, expressed on page 4, lines 17-25, that the number of large pores should be limited (at least 70% of the pores should have a pore size of less than 0.24 micron and at least 80% of pores should have a pore size less than 0.15 micron) and that the pores should not be too small (less than 20% of pores should have a pore size less than 0.014 micron).

6. Issues

The issues presented for review are:

(1) Whether claims 1 and 20 are unpatentable under 35 USC 112. However, this issue will become moot if the requested amendments to claims 1 and 20 are entered.

(2) Whether claims 1-4, 6-8, 15, 16, 20-21, 23-25 and 29 are unpatentable over U.S. Patent No. 6,376,032 under the judicially created doctrine of double patenting. However, this issue will become moot if the submitted Terminal Disclaimer is entered. [The final rejection includes claim 14 in this rejection, but this appears to be an error, since claim 14 has been withdrawn from consideration.]

(3) Whether Claims 1, 2, 7, 8, 11, 13, 15-16 and 30 are unpatentable under 35 U.S.C. 102 as anticipated by US Patent No. 5,160,768 (hereinafter "Antoon").

(4) Whether claims 2-6, 20-26, 28 and 31 are unpatentable under 35 U.S.C. 103 over Antoon.

7. Grouping of Claims

For the reasons set out below, Appellant contends that

(a) in the group of claims 1, 2, 7, 8, 11, 13, 15-16 and 30 rejected under 35 USC 102, the claims of the group do not stand or fall together, claims 15 and 30 being independently patentable; and

(b) in the group of claims 2-6, 20-26, 28 and 31 rejected under 35 USC 103, the claims of the group do not stand or fall together, claims 4, 5, 6, 21, 22, 23 and 31 being independently patentable.

8. Argument

8A. The Rejections on the ground of Double Patenting

Appellant has filed a Terminal Disclaimer of US Patent Number 6,376,032. As noted in the Final Rejection, such a terminal disclaimer overcomes these rejections.

8B. The Rejection of claims 1, 2, 7, 8, 11, 13, 15-16 and 30 under 35 U.S.C. 102,

8B1. Summary of the rejection.

Claims 1, 2, 7, 8, 11, 13, 15-16 and 30 have been rejected under 35 USC 102 over U.S. Patent No. 5,160,768 (hereinafter "Antoon"). All the claims rejected on this ground require the microporous film to have been made by the process defined in claim 1. The process defined in claim 1 is entirely different from the process disclosed in Antoon. The rejection depends, therefore, on an assertion by the Examiner that Antoon's microporous films are substantially the same as the microporous films defined in claim 1. MPEP 2113 states that, in such circumstances

> *the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi 218 USPQ 289, 292 (Fed Cir. 1983).*

The Examiner disagrees with Appellant's contention that the evidence of record does indeed establish an unobvious difference between the claimed product and the prior art product.

8B2. Summary of the Relevant Disclosure of Antoon

Antoon discloses gas-permeable membranes comprising certain microporous films and certain polymeric coatings on the films. It also discloses the use of such gas-permeable membranes as atmosphere control members in packages for respiring biological materials. Antoon's microporous films are composed of a polyolefin filled with 40 to 75% of calcium carbonate, and they are manufactured by casting a mixture of a polyolefin and a filler as a sheet, and drawing the sheet to effect orientation of the polymer. During the drawing, "the polymer pulls away from the filler material causing voids and pores to form in the film matrix". The degree of permeability that results is stated to be "a function of the amount of filler in the polymer, the amount of draw imposed upon the polymer and the temperature at which the drawing is carried out". (See column 4, lines 48-59, off Antoon.) The polymeric coating on Antoon's microporous film is composed of a cured silicone elastomer.

8B3. The Process defined in Claim 1 is Different from the Process disclosed in Antoon

Claim 1 is an independent claim, and each of claims 2, 7, 8, 11, 13, 15-16 and 30 is dependent on Claim 1. Claim 1 (and, therefore, each of claims 2, 7, 8, 11, 13, 15-16 and 30) requires that the microporous film has been prepared by a process which (as defined in more detail in claim 1) comprises passing a continuous sheet comprising a powdered polymer, a filler, and a processing oil through calender rolls to reduce its thickness; treating the calendered sheet with an organic extraction liquid which removes the processing oil; and removing the extraction liquid by steam or water or both.

The process defined in Claim 1 is, therefore, completely different from the process disclosed in Antoon for preparing microporous sheets.

8B4. Summary of the Examiner's Position.

The Examiner's position is set out in a variety of ways in the Final Rejection and Advisory Action, but Appellant believes that it can be accurately summarized as follows.

1) Antoon's microporous films appear to be substantially identical to microporous films made by the process defined in claim 1.

2) Under such circumstances, claim 1 is unpatentable under 35 USC 102, unless the applicant meets the burden of establishing an unobvious difference between the claimed product and Antoon's product.

3) Applicant has not met that burden.

If the Examiner's Answer sets out any significant difference between the summary above and her position, Appellant will address any additional issues raised thereby.

8B5. Summary of the Appellant's Position.

Appellant accepts that the burden is on Appellant to show an unobvious difference between microporous films prepared by the process defined in claim 1 and the microporous films disclosed in Antoon. Contrary to the Examiner, Appellant contends that the evidence of record does indeed discharge that burden, since it establishes

a) that the microporous films produced by Antoon's drawing process are structurally different from the microporous films produced by the claimed extraction process (they have different pore size characteristics, Antoon's products being less consistent in their pore sizes, having a wider range of pore sizes and having a greater proportion of larger pores), and

b) that when microporous films produced by the two processes are coated with a polymer, Antoon's coated products have different and inferior properties.

8B6. The Examiner's Errors in the rejection of the claims under 35 USC 102.

8B6(a). The Examiner has incorrectly relied on certain facts as providing factual proof that microporous films made by Antoon's process are the same as or similar to microporous films prepared by the process defined in claim 1.

It is correct that

(i) both the claimed gas-permeable membrane and Antoon's gas-permeable membrane comprise a microporous film and a polymeric coating on the microporous film (and that the polymeric coatings on the films can be the same), and

(ii) the claimed gas-permeable membranes and many of Antoon's gas-permeable membranes have OTR and R values greater than the minimum values required by claim 1.

Appellant does not dispute that these are facts (in the words of MPEP 2113, with emphasis added) ***tending*** *to show that the claimed product* ***appears to be*** *the same or similar* to Antoon's product. But the Examiner has incorrectly relied upon these facts as providing proof that the products are **in fact** substantially the same. For example, the Final Rejection states, in the sentence bridging pages 7 and 8 (with emphasis added),

> *... the gas-permeable membrane of (Antoon)* ***is*** *identical to or only slightly different than the gas-permeable membrane prepared by the method of the claim, because both gas-permeable membranes have a microporous polymeric film and a polymeric coating on the microporous film, both have an oxygen permeance (i.e. 0TR) of at least 775,000 ml/m^2.atm.24 hrs (50,000 cc/100 in^2.atm.24 hrs) and a CO_2 /oxygen permeability ratio (R) of at least 1.5", as required by Applicants' claim 1.*

The Advisory Action similarly states, on page 4 (again with emphasis added),

> *... Antoon discloses* ***the same*** *gas-permeable membrane made from polypropylene (column 3, lines 61) and the same polymeric coating poly(dimethylsiloxane) desired by the applicant wherein the oxygen permeance is*

at least775,000 ml/m^2.atm.24 hrs and a CO_2 /oxygen permeability ratio of at least 1.5" therefore, the 35 USC 102 rejection is maintained.

It is perhaps self-evident that, merely because two gas-permeable membranes have OTR and R values above a particular minimum, it is wrong to assert that they are necessarily the same, even if both gas-permeable membranes are composed of a microporous film composed of polypropylene and having a coating thereon of poly(dimethylsiloxane). Such assertions ignore, for example, the important effects of pore size and distribution in the microporous film (which Antoon does not consider and whose importance is demonstrated by the present invention and by the evidence). Nevertheless, for the avoidance of doubt, Appellant has provided evidence which directly contraverts the Examiner's assertions. This evidence is in paragraph 6 of the Clarke declaration, which includes the following statements.

The 0TR and R ratio of a gas permeable membrane can vary widely above the stated minimum values, and this variation can result from the use of microporous films and/or polymeric coatings which differ from each other.

Even when gas-permeable membranes have substantially the same 0TR and R ratio, they can be based on substantially different microporous films and/or substantially different polymeric coating.

and

Even when the polymeric coating is the same, gas-permeable membranes based on different microporous films can have 0TR and R values which are greater than the stated minimum values, but which are widely different from each other".

Another example of the Examiner's erroneous assertion of substantial identity between the two products is the following statement on page 7 of the Final Rejection (with emphasis added).

*Since Antoon teaches that which appears to be **identical** to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon would be inherent.*

The initial premise of this statement is that Antoon's gas-permeable membranes are **identical** to the claimed gas-permeable membranes. If that premise were correct, then of course it would also be correct that the "recited properties" are inherent in Antoon's membranes. But since it is clear (see the next section of this Appeal Brief) that there are structural differences between the claimed membranes and Antoon's membranes, the statement does not support the rejection.

8B6(b). The Examiner has incorrectly failed to give proper weight to the evidence in the Clarke declaration, and the accompanying argument, which

(a) rebuts the stated basis for the rejection, and

(b) affirmatively proves the unobvious differences between microporous films prepared by Antoon's process and microporous films prepared by the process defined in claim 1.

The Final Rejection states that the Clarke declaration *has been considered but is not persuasive,* and *does not provide evidence to show that the articles are structurally different.* However, the Examiner's basis for dismissing the evidence contained in the Clarke declaration amounts to no more than the assertions which are shown to be unjustified in section 8B6(a) above. Specific examples of the evidence apparently ignored by the Examiner include the following passages in the Clarke declaration.

1. Paragraph 9, page 5, lines 1-11.

The voids in microporous films produced by an extraction process as defined in Claim 1 have a shape which is *substantially the same as the pockets and channels of the processing oil in the polymeric matrix before the oil is removed by the extraction.* The voids in Antoon's microporous films, by contrast, *are produced in an essentially random fashion* by a drawing process which involves *sudden violent rupture of the polymeric matrix.* As a result, *the voids remaining after the extraction are ... quite different from the voids produced by Antoon's drawing process.*

2. Paragraph 10, page 5, lines 13-24.

The differences between the two processes *are reflected in the different pore size characteristics* of the resulting microporous films. In particular, microporous films produced by Antoon's process *are less consistent in their pore sizes, have a wider range of pore sizes, and have a greater proportion of larger pores. As a result, coated membranes based on Antoon's microporous sheets are inferior to coated membranes based on microporous films produced by the extraction process* of claim 1. It appears that the reason for this *is that the larger pores are not blocked (or not completely blocked) by the coating polymer, especially at the low coating weights which are preferred in order to obtain adequate oxygen permeability. As a result, the permeability characteristics of the coated membrane insufficiently reflect the properties of coating polymer.*

3. Paragraphs 11-12, page 5, line 26, to page 8, line 2.

The specific Examples of Antoon demonstrate that, as would be expected from the novel teaching of the present application, Antoon's coated membranes *suffer from the disadvantages that result from a wide range of pore sizes and the presence of substantial proportions of relatively large pores (Declaration, page 6, lines 5-8).* For example, in Antoon's coated *membranes neither the 0TR nor the R ratio is a function of the coating weight (Declaration, page 7, lines 13-15)* of the polysiloxane coating polymer, and *it is not possible, even at relatively high coating weights, to obtain a coated membrane having an R ratio which fully reflects the R ratio of the coating polymer (Declaration, page 7, lines 21-24).* By contrast, the specific Examples of the present application make it clear that, when using a microporous film prepared by the extraction process and coated with the same polysiloxane coating polymer as was used by Antoon,

(i) substantially higher R ratios are obtained (compare the R values at similar OTR values in Tables A and B on pages 6 and 7 of the Declaration), and

(ii) *there is a progressive reduction in the R ratio of the coated membrane, and a progressive increase in its 0TR value, as the coating weight ... is reduced (Declaration, page 7, lines 17-19).*

Thus, the Clarke declaration, in particular the passages summarized above, provides clear evidence that

(a) the microporous films defined in Claim 1 are structurally different from the microporous films disclosed in Antoon; and

(b) the identified structural differences are critical to the properties and performance of membranes produced by coating the microporous films with polymers.

8B6(c). The Examiner has incorrectly applied the law concerning the burden of proof.

As noted above, the Examiner has failed to give proper weight to the evidence of the Clarke declaration, and the accompanying argument. It appears that the Examiner, in so doing, has incorrectly applied the law concerning the burden of proof. In this connection, it should be noted that the CAFC stated, in *in re* Glaug and Kato, 283 F.3d 1335 (2002),

> During patent examination, the PTO has the initial burden of presenting a *prima facie* case of unpatentability. *In re* Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed Cir, 1992), *In re Piasecki, 745* F.2d 1468, 1472, 223 USPQ2d 785, 788 (Fed Cir, 1984). If the PTO fails to meet this burden, than the applicant is entitled to the patent. However, when a *prima facie* case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability. Patentability *vel non* is then determined on the entirety of the record, by a preponderance of evidence and weight of argument. Id. As discussed in *in re* Rinehart, 531 F2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976), the prima facie case is not a stone wall against which rebuttal evidence is tested; patentability is determined by a preponderance of all the evidence.

8B7. Separate patentability of claims 15 and 30

Appellant submits, for the reasons set out below, that claims 15 and 30 are separately patentable, even if the remainder of claims 1, 2, 7, 8, 11, 13, 15, 16 and 30 are unpatentable.

Claim 15 requires that the microporous polymeric film contains pores partially blocked by a polymer having an R ratio of less than 1.3 or by a particulate material. Antoon does not disclose or suggest such a microporous polymeric film.

Claim 30 requires that the filler in the microporous film is a siliceous filler. Antoon makes it clear that his microporous film must contain 40 to 75% of calcium carbonate. This is explicitly stated in the Summary of the Invention (col. 2, lines 48-49), claim 1 (col. 10, lines 9-10) and elsewhere. The Examiner has noted that col. 4, lines 60-67, of Antoon states that "a large number of inorganic materials have been shown to be effective as fillers for effecting void and pore formation", including silica. However, that disclosure is only in the context of a description of "microporous films and the preparation thereof... known in the art" (col. 4, lines 48-49); it is not part of the disclosure of the invention. The likely explanation (and therefore the teaching derived from Antoon by one skilled in the art) for Antoon's explicit choice of calcium carbonate is that microporous films using other fillers are not satisfactory.

8C. The Rejection of claims 2-6 under 35 U.S.C. 103

8C1 General

In the Final Rejection, the rejection under 35 U.S.C. 103 of claims 2-6 (which are dependent on claim 1, and which, therefore, define the microporous film by its method of preparation) is discussed together with the rejection under 35 U.S.C. 103 of the expense claims 20-26, 28 and 31 (which define the microporous film in terms of the size

and distribution of the pores). Appellant believes that the issues raised by the rejection of claims 2-6 under 35 U.S.C. 103 are different from those raised by the rejection of claims 20-26, 28 and 31, which are, therefore, discussed separately below.

8C2 The Rejection of claims 2-6 under 35 USC 103 raises the same issues as the rejection of claims 1, 2, 7, 8, 11, 13, 15, 16 and 30 under 35 USC 102

Appellant believes that the rejection of claims 2-6 under 35 USC 103 raises the same issues as the rejection under 35 USC 102 of claims 1, 2, 7, 8, 11, 13, 15, 16 and 30. For example, MPEP 2113 refers to 35 USC 102/103 in its capitalized headings, and does not distinguish between the two grounds of rejection. Appellant contends, therefore, that the rejection should be withdrawn for the reasons set out in section 8B above. If the Examiner's Answer states that the rejection under 35 USC 103 raises issues different from those raised by the rejection under 35 USC 102, Appellant will address any new issues thus raised.

8C3. Independent Patentability of Claims 4, 5 and 6

Appellant submits, for the reasons set out below, that claims 4, 5 and 6 are separately patentable, even if the remainder of claims 2-6 are unpatentable under 35 USC 103

Claim 4. Claim 4 requires that at least 90% of the pores have a pore size less than 0.24 micron. Antoon does not disclose this feature, and the evidence in paragraph 13 of the Clarke Declaration establishes that microporous films prepared by Antoon's process do not have this feature. There is, therefore, a proven structural difference between the two types of microporous film. There is nothing in Antoon to suggest the desirability of using a microporous film containing at least 90% of the pores having a pore size less than 0.24 micron. The difference is, therefore, both structural and unobvious.

Claim 5. Claim 5 requires that substantially 100% of the pores have a pore size less than 0.24 micron. Antoon does not disclose this feature, and the evidence in paragraph 13 of the Clarke Declaration establishes that microporous films prepared by Antoon's process do not have this feature. There is, therefore, a proven structural difference between the two types of microporous film. There is nothing in Antoon to suggest the desirability of using a microporous film in which substantially 100% of the pores have a pore size less than 0.24 micron. The difference is, therefore, both structural and unobvious.

Claim 6. Claim 6 requires that at least 80% of the pores have a pore size less than 0.15 micron. Antoon does not disclose this feature, and the evidence in paragraph 13 of the Clarke Declaration establishes that microporous films prepared by Antoon's process do not have this feature. There is, therefore, a proven structural difference between the two types of microporous film. There is nothing in Antoon to suggest the desirability of using a microporous film in which at least 80% of the pores have a pore size less than 0.15 micron. The difference is, therefore, both structural and unobvious.

8D. The Rejection of claims 20-26, 28 and 31 under 35 U.S.C. 103

8D1. Summary of the Rejection

Claims 20-26, 28 and 31 have been rejected under 35 USC 103 over Antoon. Each of claims rejected on this ground requires the use of a microporous film in which

(i) at least 70% of the pores have a pore size of less than 0.24 micron,

(ii) less than 20% of the pores have a pore size less than 0.014 micron, and

(iii) at least 80% of the pores have a pore size less than 0.15 micron.

The Examiner agrees that Antoon does not disclose these essential features. Nevertheless, the rejection asserts that these features are obvious having regard to Antoon and/or are inherent in Antoon's disclosure. [Like claim 1, claim 20 also requires that the pores have an average size of less than 0.24 micron, but this feature is not relied upon in support the patentability of the claims.]

8D2. Summary of the Relevant Disclosure of Antoon.

Antoon has been summarized in section 8B2 above. To that summary may be added the fact that Antoon gives no explicit information about the size and distribution of the pores in his microporous films, and that such information as he does give suggests that large pores are more desirable than small pores.

8D3. The Gas-Permeable Membranes defined in Claim 20 are Different from those disclosed in Antoon.

Claim 20 is an independent claim, and each of claims 21-26, 28 and 31 is dependent on claim 20. Claim 20 (and therefore each of claims 21-26, 28 and 31) requires the use of a microporous film in which

(i) at least 70% of the pores have a pore size of less than 0.24 micron,

(ii) less than 20% of the pores have a pore size less than 0.014 micron, and

(iii) at least 80% of the pores have a pore size less than 0.15 micron.

Antoon does not disclose that the pores in his microporous films meet any one of these requirements. Therefore, microporous films as defined in claim 20 are not disclosed in Antoon.

8D4. The Examiner's Position

In support of the rejection under 35 U.S.C. 103, the Final Rejection states

(i) that, since Antoon teaches a gas-permeable membrane having the 0TR and R ratio specified in the claims, *it would have been obvious to one of ordinary skill in the art to have provided the specified pore size and density in the microporous film*, and

(ii) that since *Antoon teaches that which appears to be identical to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon would be inherent.*

The Advisory Action adds the following statement.

(iii) *In response to Applicant's argument that the Examiner does not provide any reason or evidence of the relationship between the size and distribution of the pores in the microporous film, and the OTR and R ratio of a membrane produced by coating the microporous film a polymer, Antoon teaches that the silicone coated film must be selected to have a permeability sufficient to allow the type of control required within a reasonable time and the microporous sheet can be prepared by casting a sheet of the mixture of the polymer highly loaded with a filler material wherein the degree of permeability that results is a function of the amount of filler in the polymer wherein the particle size of filler determines the size of the pores (column 4 lines 43-column 5 lines 1-4).*

8D5. Summary of the Appellant's Position

Contrary to the Examiner's position, Appellant contends

(i) that there is nothing in Antoon to support the view that one of ordinary skill in the art, reading Antoon without knowledge of the present invention, would have found it obvious to make use of a microporous film having the pore size characteristics required by claim 20, and

(ii) that there is no basis for asserting that the pore size characteristics required by claim 20 are inherent in the disclosure of Antoon.

8D6. The Examiner's Errors in the Rejection of Claims under 35 USC 103.

8D6(a). The Examiner has failed to make a *prima facie* case that claim 20 is obvious. The first step in the rationale of the rejection is an assertion that one of ordinary skill in the art would have understood that the OTR and R values of Antoon's gas-permeable membranes are related to the pore characteristics of the microporous film. But neither Antoon nor the Examiner provides a basis for that assertion. Even if that assertion is taken to be true, neither Antoon or the Examiner provides a basis for concluding that such understanding would have

made it obvious to select a microporous film having the pore characteristics required by claim 20.

Antoon says very little about the size or other characteristics of the pores in his microporous films, and what he does say is remote from the invention defined in claim 20. The following passages in Antoon refer directly or indirectly to the size and other characteristics of the pores in Antoon's microporous films.

1) Column 3, lines 30-34, teaches that the permeability (i.e. OTR) of the microporous film should be as high as possible. Thus, this passage says that a *critical feature* is that the microporous film is at least 2 times, preferably at least 10 times, as permeable as the coating thereon. . This passage does not refer directly to any of the pore characteristics. However, insofar as it may be regarded as providing any teaching about pore characteristics, the teaching is (since larger pores result in higher permeability) that larger pores are desirable (Clarke Declaration, page 4, end of paragraph 7).

2) Column 4, lines 54-59, says that the degree of permeability depends upon the amount of filler, the amount of draw, and the temperature, thus teaching that the way to achieve the desired permeability is by control of these features.

3) Column 5, lines 6-13, of Antoon states that a *particularly useful membrane having the correct porosity characteristics... is a microporous film... comprised of about 40 to 60% of a propylene polymer mixture and 50 to 65% of calcium carbonate, biaxially or uniaxially oriented at a temperature between about 100° and 170°C that is coated with a thin layer of cured silicone elastomer.* Consistent with Column 4, lines 54-59, this passage teaches that the way to obtain a desirable microporous film is by controlling the amount of filler, the amount of draw, and the temperature. But it does nothing to identify the physical characteristics of the pores which result from controlling these features.

4) Column 3, lines 60-65, says that a uniaxially oriented polypropylene film filled with 50 to 65% of calcium carbonate is the preferred microporous film, because it *has narrow elongated pores on the surface that are more readily bridged by an intact silicone membrane*. This passage refers only to the shape of surface pores. It says nothing about the absolute size or the size distribution of the surface pores, still less of the pores in general.

5) Column 4, line 67-column 5, line 5, says that a calcium carbonate filler of average particle size 3 micron is preferable to a calcium carbonate filler of average particle size 12 micron, because it gives *smaller surface pores.* This passage refers only to the relative size of the surface pores, and say nothing about the absolute size or the size distribution of the surface pores, still less of the pores in general.

There is nothing in the passages noted above, or elsewhere in Antoon, to suggest that there is any relationship between the R ratio of the gas-permeable membrane and the size or other characteristic of the pores in the microporous film. There is nothing in the passages noted above, or elsewhere in Antoon, to suggest that the size distribution of the pores in the microporous film is important to the OTR or the R ratio, or any other property, of the gas-permeable membrane. Insofar as these passages, or anything else in Antoon, may be regarded as disclosing a relationship between the OTR of the gas-permeable membrane and the absolute size of the pores in the microporous film, the disclosed relationship is that larger pores are more desirable than smaller pores.

8D6(B). The Examiner has incorrectly failed to give proper weight to the evidence in the Clarke Declaration which affirmatively proves the unobvious advantages of the gas-permeable membranes defined in claim 20.

For the reasons set out in section 8D6(A) above, Appellant contends that the Examiner has failed to make even a *prima facie* case in support of the rejection under 35 USC 103. If that contention is accepted, then it is unnecessary to consider whether

a gas-permeable membrane as defined in claim 20 is not only novel but also advantageous. However, out of an abundance of caution, Appellant has provided evidence of the unexpected advantages resulting from the use of a microporous film having the characteristics defined in claim 20. The Examiner has incorrectly failed to give proper weight to that evidence.

Specific examples of the evidence apparently ignored by the Examiner include the following passages in the Clarke declaration.

1. Paragraphs 11-12, page 5, line 26, to page 8, line 2.

As noted in the present application at page 4, line 17-25, if the microporous film does not comply with the requirements of claim 20 (i.e. has a wide range of pore sizes and/or a substantial proportion of relatively large pores) a gas-permeable membrane made by coating the microporous film with a polymer has inferior properties. The specific Examples of Antoon show gas-permeable membranes which do indeed have such inferior properties, and thus confirm that Antoon's microporous films do not meet the requirements of claim 20. For example, in Antoon's coated *membranes neither the 0TR nor the R ratio is a function of the coating weight (Declaration, page 7, lines 13-15)* of the polysiloxane coating polymer, and *it is not possible, even at relatively high coating weights, to obtain a coated membrane having an R ratio which fully reflects the R ratio of the coating polymer (Declaration, page 7, lines 21-24).*

A comparison of specific Examples in the present application and in Antoon demonstrates the advantages of using a microporous film meeting the requirements of claim 20. A number of the specific Examples of the present application and in Antoon use the same coating polymer (Dow Corning 734 or Silastic 734). This makes it possible to compare the results obtained using different microporous films. Paragraph 12 on pages 6-7 of the Clarke Declaration provides that comparison. As noted by the Clarke declaration, when the microporous film is Teslin SP7, which meets the requirements of claim 20 (see the table on page 17 of the application)

(i) higher R ratios are obtained than when using Antoon's microporous film (compare the R values at similar OTR values in Tables A and B on pages 6 and 7 of the Declaration), and

(ii) *there is a progressive reduction in the R ratio of the coated membrane, and a progressive increase in its 0TR value, as the coating weight ... is reduced (Declaration, page 7, lines 17-19*), whereas, when using Antoon's microporous film, *neither the OTR nor the R ratio is a function of the coating weight)* and *it is not possible, even at relatively high coating weights, to obtain a coated membrane having a R ratio which fully reflects the R ratio of the coating polymer* (Declaration, page 7, lines 21-24).

Thus, the Clarke declaration, in particular the passages summarized above, provides clear evidence that the requirements of claim 20 are critical to the properties and performance of membranes produced by coating the microporous films with polymers.

8D6(c). The Examiner has incorrectly asserted that Antoon's teaching with respect to permeability is identical to that disclosed by Appellant, and has compounded that error by asserting that such identity means that the features of claim 20 are inherent in Antoon.

Both Appellant and Antoon teach that it is desirable for the permeability (OTR) of the microporous film and of the gas-permeable membrane to be high. But, as discussed in detail above, they differ very substantially in their teaching of how this desirable result can be combined with other desirable results. Even if it were true that Antoon's teaching as to permeability is identical to that disclosed by Appellant, the Examiner has not provided any rational basis for an assertion that such identity means that the requirements of claim 20, even though not disclosed in Antoon, are inherent in Antoon's gas-permeable membranes.

8D6(d). The Examiner has incorrectly applied the law concerning the burden of proof.

As in her consideration of the evidence and arguments submitted in connection with the rejection under 35 USC 102, the Examiner has failed to give proper weight to the evidence of the Clarke declaration, and the accompanying argument, submitted in connection with the rejection under 35 USC 103, and, in so doing, has incorrectly applied the law concerning the burden of proof. The directions given by the CAFC in *in re* Glaug and Kato, as quoted in Section 8B6(c) above, are equally applicable to this rejection, and need not be repeated.

Independent Patentability of Claims 21, 22, 23, and 31

Applicants submit, for the reasons set out below, that claims 21, 22, 23 and 31 are separately patentable, even if the remainder of claims 20-26, 28 and 31 are unpatentable under 35 USC 103.

Claim 21. Claim 21 requires that at least 90% of the pores have a pore size less than 0.24 micron. Antoon does not disclose or suggest this feature.

Claim 22. Claim 22 requires that substantially 100% of the pores have a pore size less than 0.24 micron. Antoon does not disclose or suggest this feature.

Claim 23. Claim 23 requires that at least 80% of the pores have a pore size less than 0.15 micron and that at least 70% of the pores have a pore size less than 0.11 micron. Antoon does not disclose or suggest this feature.

Claim 31. Claim 31 requires that the filler in the microporous film is a siliceous filler. Antoon makes it clear that his microporous film must contain 40 to 75% of calcium carbonate. This is explicitly stated in the summary of the invention (col. 2, lines 48-49), in claim 1 (col. 10, lines 9-10) and elsewhere. Column 4, lines 60-67, of Antoon states

that "a large number of inorganic materials have been shown to be effective as fillers for effecting void and pore formation", including silica. However, that disclosure is only in the context of a description of "microporous films and the preparation thereof... known in the art" (col. 4, lines 48-49); it is not part of the disclosure of the invention. The likely explanation (and therefore the teaching derived from Antoon by one skilled in the art) for Antoon's explicit choice of calcium carbonate is that microporous films using other fillers are not satisfactory.

8E. The Rejection under 35 USC 112

8E(1). Summary of the Rejection.

The Final Rejection rejects claims 1 and 20 under 35 USC 112 because there is no basis in the original disclosure for the exclusionary proviso at the end of each claim.

8E(2). The Rejection will be Moot if the Requested Amendments are Made.

The exclusionary provisos were added by way of amendment in the Reply to an earlier Office Action, in an attempt to overcome the double patenting rejection. A Terminal Disclaimer has now been filed in order to overcome the double patenting rejection, making the exclusionary provisos unnecessary. Therefore, in a paper accompanying this Appeal Brief, Appellant has requested that the provisos should be deleted. If the requested amendment is entered, and the provisos thus deleted, the rejection under 35 USC 112 will be moot.

8E(3). The Examiner's Position

The Examiner's basis for making the rejection under 35 USC 112 is that the exclusionary proviso is a negative limitation that does not have basis in the original disclosure, and should, therefore, be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

8E(4). The Appellant's Position

Appellant contends that there is basis in the application as filed for the proviso. The specification as filed makes it clear that the gas-permeable membranes of the invention can comprise a microporous film as defined in claim 1 or claim 20 and **any** polymer coated thereon. The specification as filed also makes it clear that the polymer can be a crystalline polymer as defined in the proviso, as well as other polymers (page 8, line 15, to page 9, line 12, page 10, line 29, to line 11, line 21, and page 12, lines 14-60). Thus the proviso merely excludes from the group of polymers in general, for which there is explicit basis, a defined class of crystalline polymers, for which there is likewise explicit basis. The proviso does not introduce any new concept. Thus, it is clear that the amended claims meet the written description requirement of 35 USC 112. It is also relevant that the sole purpose of the proviso is to prevent overlap with an earlier issued patent. It is not required in order to overcome a rejection under 35 USC 102 of 35 USC 103.

Conclusion

Appellant submits that for the reasons set out above, the rejections should be withdrawn and a patent issued.

Respectfully submitted,

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Docket No. 10621-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Clarke et al

Serial No. 09/976,987 Group Art Unit: 1772

Filing Date: Oct. 12, 2001 Examiner Rhee, Jane J

Title: Gas-permeable Membrane

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Commissioner for Patents

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APPENDIX TO APPEAL BRIEF

This Appendix contains a copy of the claims involved in the appeal.

1. A gas-permeable membrane which is useful in the packaging of respiring biological materials and which comprises

(a) a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film, and

(b) a polymeric coating on the microporous film,

wherein

(1) the pores in the microporous film have an average pore size of less than 0.24 micron; and

(2) the microporous film was prepared by a process comprising the steps of

(A) preparing a uniform mixture comprising a polymeric matrix material in the form of a powder, a finely divided, particulate, substantially water-insoluble filler, and a processing oil;

(B) extruding the mixture as a continuous sheet;

(C) forwarding the continuous sheet, without drawing, to a pair of heated calender rolls;

(D) passing the continuous sheet through the calender rolls to form a sheet of lesser thickness;

(E) passing the sheet from step (D) to a first extraction zone in which the processing oil is substantially removed by extraction with an organic extraction liquid which is a good solvent for the processing oil, a poor solvent for the polymeric matrix material, and more volatile than the processing oil;

(F) passing the sheet from step (E) to a second extraction zone in which the organic extraction liquid is substantially removed by steam or water or both; and

(G) passing the sheet from step (F) through a forced air dryer to remove residual water and organic extraction liquid; and

(3) the polymeric coating has a thickness such that the membrane

(i) has a P_{10} ratio, over at least one 10 °C range between -5 and 15°C, of at least 1.3;

(ii) has an oxygen permeability (OTR), at all temperatures between 20 and 25 °C, of at least 775,000 ml/m^2.atm.24 hrs (50,000 cc/100 $inch^2$.atm.24 hrs; and

(iii) has a CO_2/O_2 permeability ratio(R) of at least 1.5;

the P_{10}, OTR and R values being measured at a pressure of 0.035 kg/cm^2 (0.5 psi).

subject to the proviso that the polymeric coating does not comprise a crystalline polymer having a peak melting temperature T_p of -5 to 40 °C, an onset of melting temperature T_o such that ($T_p - T_p$) is less than 10 °C, and a heat of fusion of at least 5 J/g.

Note. If the amendments requested in the Amendment filed with the Appeal Brief are entered, the last three lines of this claim (beginning with the words "subject to the proviso..." and ending with the words "... at least 5 J./g.") will be canceled.

2. A membrane according to claim 1 wherein the polymeric matrix material is selected from the group consisting of

(i) an essentially linear ultrahigh molecular weight polyethylene having an intrinsic viscosity of at least 18 deciliters/g and

(ii) an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g.

3. A membrane according to claim 1 wherein at least 70% of the pores in the microporous film have a pore size of less than 0.24 micron.

4. A membrane according to claim 1 wherein at least 90% of the pores in the microporous film have a pore size of less than 0.24 micron.

5. A membrane according to claim 1 wherein substantially 100% of the pores in the microporous film have a pore size of less than 0.24 micron.

6. A membrane according to claim 1 wherein at least 80% of the pores in the microporous film have a pore size less than 0.15 micron.

7. A membrane according to Claim 1 which has an OTR of at least 1,550,000 ml/m^2.atm.24 hrs (100,000 $cc/inch^2$.atm.24 hrs), and an R ratio of at least 2, the OTR and R values being measured at a pressure of 0.7 kg/cm^2 (10 psi).

8. A membrane according to claim 7 which has an OTR of at least 2,325,000 ml/m^2.atm.24 hrs (150,000 cc/100 $inch^2$.atm.24 hrs) measured at a pressure of 0.7 kg/cm^2 (10 psi).

11. A membrane according to claim 1 wherein the coating polymer is polydimethyl siloxane.

13. A membrane according to claim 1 wherein the coating polymer has been crosslinked.

15. A membrane according to claim 1 wherein the microporous polymeric film contains pores which are partially blocked by a polymer having an R ratio of less than 1.3 or by a particulate material, or (b) has an OTR before coating of less than 15,500,000 (1,000,000).

16. A package which is stored in air and which comprises

(a) a sealed container, and

(b) within the sealed container, a respiring biological material and a packaging atmosphere around the biological material;

the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one said permeable control section being a gas-permeable membrane as defined in claim 1.

20. A gas-permeable membrane which is useful in the packaging of respiring biological materials and which comprises

(a) a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film, and

(b) a polymeric coating on the microporous film,

wherein

(1) the pores in the microporous film have an average pore size of less than 0.24 micron;

(2) at least 70% of the pores in the microporous film have a pore size of less than 0.24 micron;

(3) less than 20% of the pores in the microporous film have a pore size less than 0.014 micron;

(4) at least 80% of the pores in the microporous film have a pore size less than 0.15 micron; and

(5) the polymeric coating has a thickness such that the membrane

(i) has a P_{10} ratio, over at least one 10°C range between -5 and 15 °C, of at least 1.3;

(ii) has an oxygen permeability (OTR), at all temperatures between 20° and 25°C, of at least 775,000 ml/m^2.atm.24 hrs (50,000 cc/100 $inch^2$.atm.24 hrs; and

(iii) has a CO_2/O_2 permeability ratio(R) of at least 1.5;

the P_{10}, OTR and R values being measured at a pressure of 0.035 kg/cm^2 (0.5 psi). ;

~~subject to the proviso that the polymeric coating does not comprise a crystalline polymer having a peak melting temperature T_p of -5 to 40 °C, an onset of melting temperature T_o such that (T_p — T_p) is less than 10 °C, and a heat of fusion of at least 5 J/g.~~

Note. If the amendments requested in the Amendment filed with the Appeal Brief are entered, the last three lines of this claim (beginning with the words "subject to the proviso..." and ending with the words "... at least 5 J./g.") will be canceled.

21. A membrane according to claim 20 wherein at least 90% of the pores in the microporous film have a pore size less than 0.24 micron.

22. A membrane according to claim 20 wherein substantially 100% of the pores in the microporous film have a pore size less than 0.24 micron.

23. A membrane according to claim 20 wherein at least 80% of the pores in the microporous film have a pore size less than 0.15 micron and at least 70% of the pores in the microporous film have a pore size less than 0.11 micron.

24. A membrane according to claim 20 which has an OTR at all temperatures between 20°C and 25°C of at least 1,550,000 ml/m^2.atm.24 hrs (100,000 cc/$inch^2$.atm.24 hrs) and an R ratio of at least 2.5, the OTR and R values being measured at a pressure of 0.035 kg/cm^2 (0.5 psi).

25. A membrane according to claim 20 which has an OTR of at least 2,325,000 ml/m^2.atm.24 hrs (150,000 cc/100 $inch^2$.atm.24 hrs) measured at a pressure of 0.07 kg/cm^2 (10 psi).

26. A membrane according to claim 20 wherein the coating polymer is polydimethyl siloxane.

28. A membrane according to claim 20 wherein the coating polymer has been crosslinked.

29. A package which is stored in air and which comprises

(a) a sealed container, and

(b) within the sealed container, a respiring biological material and a packaging atmosphere around the biological material;

the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one said permeable control section being a gas-permeable membrane as defined in claim 20.

30. A membrane according to claim 1 wherein the filler is a siliceous filler.

31. A membrane according to claim 20 wherein the microporous polymeric film comprises a polymeric matrix having a siliceous filler dispersed therein.

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